

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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IN THE MATTER OF:

RAINBOW ACRES FARM

)
) Docket No. 10-647-M
)
)

APPLICATION FOR ADMINISTRATIVE WARRANT FOR INSPECTION

The United States of America, through the United States Attorney's Office for the Eastern District of Pennsylvania, on behalf of the Food and Drug Administration (FDA); hereby applies for an Administrative Warrant to inspect the following premises at

Rainbow Acres Farm
26 South Kinzer Road,
Kinzers, Pennsylvania, 17535

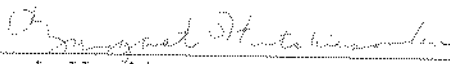
FILED
FEB 15 2010
MICHAEL KUPZ, Clerk
By [Signature] Dep. Clerk

As described in greater detail in the accompanying Declaration of FDA investigator Joshua Schafer, the FDA has reason to believe that Rainbow Acres Farm is engaged in the processing, packaging, holding and shipment of milk engaged in interstate commerce. Pursuant to 21 U.S.C. § 374, FDA investigators are authorized to enter and inspect without a warrant any establishment in which foods are processed for introduction into interstate commerce. On February 4, 2010, investigator Schafer and his partner attempted to inspect the Rainbow Acres Farm, but were denied access by the owner, Daniel Allgyer. Because consent was refused, the FDA now seeks a warrant before it proceeds with the inspection.


WHEREBY, the United States respectfully requests that the Court issue an administrative warrant for inspection of the Rainbow Acres Farm in substantially the form of the attached warrant.

Respectfully Submitted,

MICHAEL L. LEVY
United States Attorney



Margaret L. Hutchinson
Chief, Civil Division
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IN THE MATTER OF:

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DECLARATION IN SUPPORT OF APPLICATION FOR ADMINISTRATIVE WARRANT

I, Joshua C. Schafer, hereby declare as follows:

1. I am an investigator of the Philadelphia District Office, United States Food and Drug Administration (FDA), United States Department of Health and Human Services, and submit this information in support of an application for an administrative inspection warrant pursuant to the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 374 for the following establishment:

Rainbow Acres Farm
26 South Kinzer Road
Kinzers, Pennsylvania 17535

2. Rainbow Acres Farm (Rainbow Acres) is a working dairy farm and the site of milking operations and the housing of cows. As the result of an ongoing investigation, FDA has reason to believe that Rainbow Acres is engaged in the processing, packaging, holding, and shipment of milk in interstate commerce. The farm is located in Kinzers, Pennsylvania, and is the family farm of Daniel L. and Rachael Allgyer. Their private residence is also located on the farm.

3. The FDA is responsible for, among other things, conducting inspections and collecting samples from FDA-regulated industries. This is consistent with the Act's "overriding purpose to protect the public health." United States v. An Article of Drug, . . . Bacto-Unidisk, 394 U.S. 794 (1969). Milk is regulated by FDA as a food. 21 U.S.C. § 321(f).

4. Pursuant to 21 U.S.C. § 374(a)(1),¹ duly designated FDA employees are authorized to enter and inspect any establishment in which foods are processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such foods in interstate commerce.

FDA's Inspectional Authority Under 21 U.S.C. § 374

5. An inspection performed pursuant to 21 U.S.C. § 374 does not require an inspection warrant. Wedgewood Village Pharmacy, Inc. v. United States, 421 F.3d 263, 266 (3d Cir. 2005); United States v. Argent Chem. Labs., Inc., 93 F.3d 572, 577-78 (9th Cir. 1996). If a party does not consent to an inspection, however, courts have held that "FDA [is] obliged to obtain an administrative warrant in order to effect the inspection" United States v. Jamieson-McKames Pharms., Inc., 651 F.2d 532, 540 (8th Cir. 1981), cert. denied, 455 U.S. 1016 (1982).

6. Additionally, the Third Circuit Court of Appeals has held that FDA has the authority to inspect to determine if it has jurisdiction over the establishment. See Wedgewood Village Pharmacy, 421 F.3d at 273 (finding that FDA does not need to rely on a firm's claim that it is excepted from FDA's inspection authority).

7. On February 4, 2010, FDA investigator Deborah G. Haney and I traveled to Rainbow Acres in order to conduct an FDA inspection. The first structure on the left side of the driveway appeared to be a refrigerated trailer. Right next to the trailer appeared to be a cattle barn and/or milking parlor. There were two additional structures on the opposite (right) side of the driveway. The residence sat at the end of the driveway.

8. A man who presented himself as Daniel L. Allgyer, owner of Rainbow Acres, approached us. We displayed our credentials and issued a Notice of Inspection, Form FDA-482 (Form-482), to Mr.

¹ The first sentence of 21 U.S.C. § 374(1)(1) provides in pertinent part:

For purposes of enforcement of this chapter, officers or employee duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle, being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein

Allgyer. I explained to him that we were there to conduct an inspection of his milk producing operation. After Mr. Allgyer asked why were doing an inspection, I responded that FDA had reason to believe milk was being produced at this location and offered for sale to the public. Mr. Allgyer responded, "I don't produce food for the public so you don't have any reason to be here." Investigator Haney explained to

Mr. Allgyer that the FDA has authority to perform an inspection because milk is produced on and hauled away from his farm.⁷ *I have reviewed evidence showing that milk from Rainbow Farm has been sold outside Pennsylvania.* The FDA, therefore, believes that the milk is being shipped in interstate commerce. *JLS 4/19/10*

Mr. Allgyer did not confirm or deny the statement whether milk from his farm is shipped interstate. 9. I again explained to Mr. Allgyer that we were at Rainbow Acres farm to conduct an inspection. In an attempt to explain FDA's authority to conduct inspections, I read to Mr. Allgyer the first paragraph of the first sentence of 21 U.S.C. § 374(a). Mr. Allgyer shook his head no. He said we should call his lawyer who would explain why we could not inspect his farm. When I asked if he was the sole proprietor, Mr. Allgyer responded that it was just him and his wife, Rachael. Mr. Allgyer then instructed us to call his attorney with the number he provided. When I explained to Mr. Allgyer that FDA did not need to speak to his lawyer to perform an inspection, he said he wouldn't allow an inspection or answer any questions. Mr. Allgyer then said, "I want you to leave." We immediately proceeded to our government vehicle and left the property.

Request for a Warrant

10. FDA seeks to inspect Rainbow Acres to determine the scope and extent of its food production and processing operations, to evaluate the manufacturing practices it uses to produce milk, and to determine its compliance with the Act and applicable regulations.

11. As the experiences described above in paragraphs 8 and 9 illustrate, FDA cannot conduct a complete and effective inspection of Rainbow Acres without a warrant for inspection. At the time Investigator Haney and I were asked to leave the Rainbow Acres property, our inspection was incomplete because we were denied access to inspect any buildings, manufacturing equipment, and processes on the premises. We were also unable to either observe dairy cows or ask questions concerning the interstate distribution of milk.

12. Therefore, the FDA seeks an Administrative Inspection Warrant for entry to all locations of Rainbow Acres Farm (except the private residence), 26 South Kinzer Road, Kinzers, Pennsylvania, for the following purposes: (1) to inspect all portions of Rainbow Acres Farm's facilities, and all things

therein, including all equipment, materials, containers, and labeling, bearing on whether milk may be adulterated or misbranded within the meaning of the Act; (2) to enter and inspect any vehicle being used to transport or hold such food in interstate commerce; (3) to collect samples as deemed necessary by FDA, and (4) to take photographs as deemed necessary by FDA. We do not seek access to the Allgyer's private residence at this address.

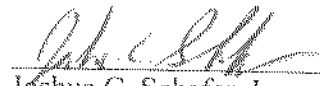
Process for Inspection after Issuance of the Warrant

13. FDA will conduct the planned inspection during regular business hours for a dairy farm. *In my experience, such hours on a dairy farm begin at 4:00 A.M.* *JCS 4/19/10*
FDA will begin the inspection as soon as practicable after issuance of the warrant and will complete the inspection with reasonable promptness. FDA will present written Notices of Inspection and appropriate credentials as prescribed by 21 U.S.C. § 374(a), and present a receipt for any and all samples collected during the inspection.

14. As the investigator, I may be accompanied by one or more additional duly authorized FDA investigators, agents, and/or local law enforcement officers. A Deputy United States Marshal may also accompany the investigator(s).

15. A return will be made to the Court within ten (10) days after the completion of the inspection.

I hereby declare that the foregoing declaration is true and correct to the best of my knowledge and belief, and is given under the penalty of perjury pursuant to 28 U.S.C. § 1746.


Joshua C. Schafer, Investigator
U.S. Food and Drug Administration

*Signed & Sworn
before me on
April 19, 2010*


U.S. Magistrate Judge